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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/117,357	09/22/98	STOCKEMANN	

EXAMINER	
K SCH1655	
ART UNIT	**PAPER NUMBER**
1614	10

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DATE MAILED: 05/26/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/117,357	Stockmann et al.
Examiner	**Group Art Unit**
Delacroix-Muirhead	1614

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- [x] Responsive to communication(s) filed on 2/14/00.
- [x] This action is FINAL.
- [ ] Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- [x] Claim(s) 10 - 39 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- [x] Claim(s) 34 - 36 is/are allowed.
- [x] Claim(s) 10 - 33, 37 - 39 is/are rejected.
- [ ] Claim(s) _____ is/are objected to.
- [ ] Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- [ ] See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- [ ] The proposed drawing correction, filed on _____ is [ ] approved [ ] disapproved.
- [ ] The drawing(s) filed on _____ is/are objected to by the Examiner.
- [ ] The specification is objected to by the Examiner.
- [ ] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- [x] Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).
  - [x] All [ ] Some* [ ] None of the CERTIFIED copies of the priority documents have been
  - [x] received.
  - [ ] received in Application No. (Series Code/Serial Number) _____.
  - [ ] received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

- [x] Information Disclosure Statement(s), PTO-1449, Paper No(s). 7
- [x] Notice of Reference(s) Cited, PTO-892
- [ ] Notice of Draftsperson's Patent Drawing Review, PTO-948
- [ ] Interview Summary, PTO-413
- [ ] Notice of Informal Patent Application, PTO-152
- [ ] Other _____

Office Action Summary

DETAILED ACTION

The following is responsive to Applicant's amendment received Feb. 14, 2000.

Claims 1-9 are cancelled. New claims 10-39 are added.

All previous claim objections and rejections set forth in paragraphs 3-6 of the office action mailed July 27, 1999, **are withdrawn** in view of Applicant's amendment and the remarks contained therein.

New Ground of Rejection

In view of Applicant's amendment, the following rejection is submitted hereinbelow:

Claim Objections

1. Claim 32 is objected to because of the following informalities: the phrase --said LHRH analogue is-- is missing from line 1. Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 10-13, 22, 37 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Walker et al (of record herein).

Walker et al. disclose pharmaceutical compositions comprising an LHRH agonist, Zoladex in combination with an anti-estrogen, tamoxifen citrate. Said composition are administered to breast cancer patients for up to 12 months. Please see the abstract.

Claim 37 is anticipated by Walker because Walker discloses administration of an identical LHRH analogue and anti-estrogen to a host using Applicant's claimed method steps. Accordingly, inhibition of the side effects associated with administration of an LHRH analogue is inherent.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to

the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 19, 31, 33 rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al., supra.

Walker as applied above.

Walker does not specifically disclose a product having spatially, separated packaged LHRH analogue and anti-estrogen with instructions; however, it would have been obvious in view of the combination therapy disclosed in Walker to modify the composition into a packaged product because modification of known LHRH analogue/anti-estrogen compositions into kits with instructional material is not novel or unobvious and well within the capability of the skilled artisan.

7. Claims 10-33, 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dodge, 5,843,962 in view of Labrie et al., 5,395,842.

Dodge discloses a method of treating gynecological disorders such as ovarian dysgenesis, wherein said method comprises administering a composition comprising an effective amount of Raloxifene in combination with an LHRH agonist. Please see the abstract; col.2 ,lines 43-56; col. 4, lines 55-56. Dodge further discloses that Raloxifene is administered in dosage amounts ranging from .1 to 1000 mg/day and that the compositions may be administered orally or intravenously. See col. 2, line 65 to col. 3, line 4.

Dodge does not disclose a method for treating endometrioses; however, the Examiner refers to Labrie et al., which discloses anti-estrogen compounds that may be useful in treating a variety of disorders including endometriosis. Please see the abstract; col. 4, lines 19-24.

It would have been obvious to one of ordinary skill in the art to modify the method of Dodge to treat endometrioses because Labrie raises reasonable expectation of success by disclosing that anti-estrogens would be effective in treating such a gynecological disorder. Such a modification would have been motivated by the reasoned expectation of successfully treating endometriosis. Furthermore, one of ordinary skill in the art would expect that the synergistic effect of the LHRH agonist and anti-estrogen would be effective in treating other gynecological disorders including endometriosis disclosed by Labrie.

Concerning the claims drawn to specific LHRH analogs, it would have been obvious to one of ordinary skill in the art to determine any number of known LHRH analogues that would be equally effective in treating gynecological disorders, such as those disclosed in the prior art.

In addressing claims drawn to an article of manufacture, it would have been obvious in view of the combination therapy disclosed in Dodge to modify the composition into a packaged product because modification of known LHRH analogue/anti-estrogen compositions into kits with instructional material is not novel or unobvious and well within the capability of the skilled artisan.

Finally, treatment of myomas would be obvious in view of the prior art's teaching of using LHRH analogues and anti-estrogens in the treatment of various gynecological disorders. Additonally, inhibition of the side effects associated with administration of LHRH analogues would have been obvious because the prior art discloses administration of substantially identical

LHRH analogues and anti-estrogens using substantially identical method steps claimed by Applicant.

Allowable Subject Matter

Claims 34-36 are free from the prior art.

Conclusion

Claims 10-33, 37-39 are rejected.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Cintins, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

CDM

May 22, 2000

MARIANNE M. CINTINS
SUPERVISORY PATENT EXAMINER
GROUP 120